A Phase III randomized double-blind, controlled study of ICT 107 with maintenance temozolomide (TMZ) in newly diagnosed glioblastoma following resection and concomitant TMZ chemoradiotherapy

Grant Award Details

A Phase III randomized double-blind, controlled study of ICT 107 with maintenance temozolomide (TMZ) in newly diagnosed glioblastoma following resection and concomitant TMZ chemoradiotherapy

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-08280

Project Objective: Phase III trial completed

Investigator:

Name:	Anthony Gringeri
Institution:	ImmunoCellular Therapeutics
Type:	PI

Disease Focus: Brain Cancer, Cancer, Solid Tumors

Human Stem Cell Use: Cancer Stem Cell

Award Value: $5,391,016

Status: Closed

Grant Application Details

Application Title: A Phase III randomized double-blind, controlled study of ICT 107 with maintenance temozolomide (TMZ) in newly diagnosed glioblastoma following resection and concomitant TMZ chemoradiotherapy

Public Abstract:

Therapeutic Candidate or Device

Autologous dendritic cells pulsed with HLA-specific peptides derived from tumor-associated antigens

Indication

Newly diagnosed glioblastoma

Therapeutic Mechanism

Autologous dendritic cells charged with peptides derived from tumor-associated antigens drive the formation of T cells that specifically target cancer stem cells and tumor cells

Unmet Medical Need

Patients with glioblastoma, a rare brain cancer with orphan status, have a poor prognosis and limited lifespan despite current standard of care. Treatment options are limited to surgery, radiotherapy and a single chemotherapeutic agent. Tumor stem cells are resistant to current standard of care.

Project Objective

Phase III trial completed

Major Proposed Activities

- Manufacture autologous therapeutic product for each patient in the Phase III trial
- Conduct a multi-center, international Phase III clinical trial showing conclusive safety and efficacy of ICT-107 for newly diagnosed glioblastoma

Statement of Benefit to California:

Glioblastoma is a deadly orphan disease whose patients have a dire prognosis, limited lifespan, and few therapeutic options. Over a thousand patients annually are diagnosed with glioblastoma in California. If ICT-107 proves effective in this Phase III trial, it will lead to increased survival, better quality of life, and potential cures many of these patients. Furthermore, success of the dendritic cell-based immunotherapy in this trial could lead to similar treatments for other tumor types.

Source URL: https://www.cirm.ca.gov/our-progress/awards/phase-iii-randomized-double-blind-controlled-study-ict-107-maintenance